

Please Rescan DTW 10/1/04

<b>Notice of References Cited</b>	Application/Control No. 09/922,327	Applicant(s)/Patent Under Reexamination KOTIN ET AL.	
	Examiner Dave T. Nguyen	Art Unit 1632	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,604,090	02-1997	Alexander et al.	435/5
	B	US-6,165,781	12-2000	Carter et al.	435/320.1
	C	US-6,342,390	01-2002	Wiener et al.	435/325
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

*Please Rescan*  
*10/1/04*

<b>Notice of References Cited</b>	Application/Control No. 09/922,327	Applicant(s)/Patent Under Reexamination KOTIN ET AL.	
	Examiner Dave T. Nguyen	Art Unit 1632	Page 1 of 1

U.S. PATENT DOCUMENTS				Classification
*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	
	A US-5604090	02-1997	Alexander	435/5
	B US-6165781	12-2000	Carter	435/320.1
	C US-6432390	01-2002	Weiner <i>Wiener</i>	435/325
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			

FOREIGN PATENT DOCUMENTS					Classification
*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	
	N				
	O				
	P				
	Q				
	R				
	S				
	T				

NON-PATENT DOCUMENTS	
*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U
	V
	W
	X

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office  
 PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 2003922



US006342390B1

(12) **United States Patent**  
Wiener et al.

(10) Patent No.: **US 6,342,390 B1**  
(45) Date of Patent: **\*Jan. 29, 2002**

(54) **LIPID VESICLES CONTAINING  
ADENO-ASSOCIATED VIRUS REP PROTEIN  
FOR TRANSGENE INTEGRATION AND  
GENE THERAPY**

(75) Inventors: **Stephen M. Wiener**, Bethesda; **John A. Chiorini**; **Brian Safer**, both of Silver Spring; **Robert M. Kotin**, Rockville, all of MD (US); **Matthew D. Weitzman**, La Jolla, CA (US); **Roland A. Owens**, Arlington, VA (US)

(73) Assignee: **The United States of America as represented by the Secretary of Health and Human Services**, Washington, DC (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **08/344,729**

(22) Filed: **Nov. 23, 1994**

(51) Int. Cl.<sup>7</sup> ..... **C12N 15/00**

(52) U.S. Cl. .... **435/325; 435/320.1; 435/372.3; 435/455; 435/458; 514/2; 514/44; 424/93.1; 424/93.21; 530/350**

(58) Field of Search ..... **435/320.1, 172.3, 435/240.1, 240.2, 240.25, 455, 458, 325-372.3; 424/93.1, 93.21; 514/44, 2; 530/350**

(56) **References Cited**

#### U.S. PATENT DOCUMENTS

5,139,941 A \* 8/1992 Muzyczka et al. .... 435/455  
5,354,678 A 10/1994 Lebkowski et al. .... 435/455  
5,436,146 A \* 7/1995 Shenk et al. .... 435/172.3  
5,474,935 A \* 12/1995 Chatterjee et al. .... 435/320.1  
5,587,308 A \* 12/1996 Carter et al. .... 435/371  
5,658,785 A \* 8/1997 Johnson ..... 435/367  
5,861,314 A \* 1/1999 Philip et al. .... 435/372.3

#### FOREIGN PATENT DOCUMENTS

WO 9324641 \* 12/1993  
WO WO 94/28157 12/1994  
WO 9507995 \* 3/1995  
WO WO 95/13365 5/1995  
WO WO 95/13392 5/1995  
WO WO 95/14771 6/1995

#### OTHER PUBLICATIONS

Marshall, Science, 269, 1995, 1050-1055.\*  
Kotin, Hum. Gene Ther., 5, 1994, 793-801.\*  
Xiao et al., Adv. Drug. Del. Reviews, 12, 1994, 201-215.\*  
Page et al., J. Cell. Biochem., 18A, 1994, 228.\*

Nahreini et al., Gene, 119, 1992, 265-272.\*

Weitzman et al., PNAS, 91, 1994, 5808-5812.\*

Srivastava et al., PNAS, 86, 1989, 8078-8082.\*

Chiorini et al., J. Virology, 68, 1994, 797-804.\*

Philip et al., Mol. and Cell. Biol., 14(4), 1994, 2411-2418.\*

Kotin et al., EMBO J., 11(13), p. 5071-5078, 1992.\*

Hermonat et al., Proc. Nat. Acad. Sci., 81:6466-6470, 1984.\*

McLaughlin, et al., J. Virology, 62(6):1963-1973, 1988.\*

Wang et al., J. Virology, vol. 68, No. 8, pp. 4847-4856, 1994.\*

Im, et al., Cell, vol. 61, pp. 447-457 (May 4, 1990).

Ghosh, et al., "Targeting of Liposomes to Hepatocytes" in *Liver Disease*, Wu, et al., eds, Marcel Dekker, Inc., New York, pp. 97-103 (1991).

Snyder, et al., J. Virol., vol. 67, No. 10, pp. 6096-6104 (Oct. 1993).

Chiorini, et al., J. Virol., vol. 68, No. 2, pp. 797-804 (Feb. 1994).

Philip, et al., Mol. Cell. Biol., vol. 14, No. 4, pp. 2411-2418 (Apr. 1994).

Chiorini, et al., J. Virol., vol. 68, No. 11, pp. 7448-7457 (Nov. 1994).

\* cited by examiner

Primary Examiner—Dave T. Nguyen

(74) Attorney, Agent, or Firm—Leydig, Voit, & Mayer, Ltd.

(57) **ABSTRACT**

A composition for delivering at least one DNA sequence encoding a desired protein or polypeptide (such as a therapeutic agent) to a cell. The composition comprises an adeno-associated virus rep protein (or a nucleic acid sequence encoding an adeno-associated virus rep protein) and a genetic construct including at least one DNA sequence encoding a protein or polypeptide or genetic transcript of interest and a promoter controlling the at least one DNA sequence. The genetic construct also includes a first adeno-associated virus ITR or protein or derivative thereof and a second adeno-associated virus ITR or a portion or derivative thereof. The first and second adeno-associated virus ITRs or portions or derivatives thereof flank the at least one DNA sequence encoding the protein or polypeptide or genetic transcript of interest and the promoter controlling the at least one DNA sequence encoding the protein or polypeptide or genetic transcript of interest. Such a composition provides for integration of genetic material at a specific locus in the human chromosome, while minimizing the possibility of inadvertent inactivation of host genes and minimizing the possibility of viral contamination.

**18 Claims, 13 Drawing Sheets**